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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/728,244      | 12/04/2003  | Roger A. Fujimoto    | 4-30188E            | 7807             |

1095 7590 09/12/2005

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

OWENS, AMELIA A

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

*He*

**Office Action Summary**

Application No.

10/728,244

Applicant(s)

FUJIMOTO ET AL.

Examiner

Amelia A. Owens

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1625

#### DETAILED ACTION

1. Claims 1-19 are pending. Drawings were not filed. Foreign priority was not claimed.

#### *Election*

2. Applicant's election with traverse of Group I, species of 1d appearing at page 24 of the specification in the reply filed on December 13, 2004 is acknowledged. The traversal is on the ground(s) that previous applications with similar scope were examined without restriction.

Upon reconsideration, the examiner is withdrawing the restriction and all claims will be examined.

#### *Double Patenting*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claim 19 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19 of prior U.S. Patent No. 6,291,523 B1. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,310,099 B1 (Fujimoto et

Art Unit: 1625

al). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

Fujimoto et al generically disclose arylaminophenylacetic acid compounds as are instantly claimed and their use as selective COX-2 cyclooxygenase inhibitors. See claims; abstract.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the Fujimoto genus in order to obtain additional beneficial COX-2 cyclooxygenase inhibitors. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Fujimoto in the expectation of obtaining a useful COX-2 cyclooxygenase inhibitor as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

The species claims are included as the genus of the reference is so limited that they would be immediately apparent to one of ordinary skill in the art.

5. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,451,858 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

Fujimoto et al generically disclose arylaminophenylacetic acid compounds as are instantly claimed and their use as selective COX-2 cyclooxygenase inhibitors. See claims; abstract.

Art Unit: 1625

One of ordinary skill in the art would thus be motivated to prepare compounds from under the Fujimoto genus in order to obtain additional beneficial selective COX-2 cyclooxygenase inhibitors. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Fujimoto in the expectation of obtaining a useful selective COX-2 cyclooxygenase inhibitors as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

The species claims are included as the genus of the reference is so limited that they would be immediately apparent to one of ordinary skill in the art.

6. Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,727,281 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

Fujimoto et al generically disclose arylaminophenylacetic acid compounds as are instantly claimed and their use as selective COX-2 cyclooxygenase inhibitors. See claims; abstract.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the Fujimoto genus in order to obtain additional beneficial selective COX-2 cyclooxygenase inhibitors. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Fujimoto in the expectation of obtaining a useful selective COX-2 cyclooxygenase inhibitors as compounds structurally similar in structure are

Art Unit: 1625

expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

The species claims are included as the genus of the reference is so limited that they would be immediately apparent to one of ordinary skill in the art.

Further, Fujimoto teach the same process for preparing said compounds. Compare claim 17 with instant claim 19. The difference is the language. The resulting process is the same.

7. Claims 1-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-36, of U.S. Patent No. 6,291,523 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

Fujimoto et al generically disclose arylaminophenylacetic acid compounds as are instantly claimed and their use as selective COX-2 cyclooxygenase inhibitors. See claims; abstract.

One of ordinary skill in the art would thus be motivated to prepare compounds from under the Fujimoto genus in order to obtain additional beneficial selective COX-2 cyclooxygenase inhibitors. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Fujimoto in the expectation of obtaining a useful selective COX-2 cyclooxygenase inhibitors as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

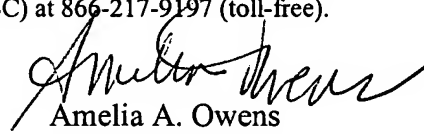
The species claims are included as the genus of the reference is so limited that they would be immediately apparent to one of ordinary skill in the art.

Art Unit: 1625

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens  
Primary Examiner  
Art Unit 1625